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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/101,518	12/21/1998	YI LI	PF218US	9737
22195	7590	04/06/2004	EXAMINER	
HUMAN GENOME SCIENCES INC INTELLECTUAL PROPERTY DEPT. 14200 SHADY GROVE ROAD ROCKVILLE, MD 20850			PAK, MICHAEL D	
			ART UNIT	PAPER NUMBER
			1646	

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/101,518	LI, YI	
	Examiner	Art Unit	
	Michael Pak	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2003.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-128 is/are pending in the application.
4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 29-32, 51-55, 64, 74-78, 97-101, 110, 120-123, 127 and 128 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/16/03</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 33-50,56-63,65-73,79-96,102-109,111-119 and 124-126.

DETAILED ACTION

Response to Amendment

1. Amendment filed 16 December 2003 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant's arguments filed 16 December 2003, have been fully considered but they are not found persuasive.
4. Applicants traverse the restriction of claims 14-18 because Marchese et al. has been now antedated by Declaration of Yi Li under 37 CFR 1.131. However, the Declaration of Yi Li is not persuasive because the claims fails to provide adequate support under 35 U.S.C. 112 for claims 29-32, 51-55, 64, 74-78, 97-101, 110, 120-123 and 127-128 of this application for the reasons provided below and in previous office actions. See MPEP 706.02. Applicants further argue that the lack of unity should be only for the elected group 3. However, the lack of unity was determined previously with the original claims and special technical feature was determined to be lacking at the time of lack of unity issued. Applicants argue that it would not be a search burden. However, each of the groups have acquired a special status in the art because of their divergent subject matter. Furthermore, the classification would be in different classification.

The requirement is still deemed proper and is therefore made FINAL.

Declaration

5. The Declaration of Yi Li filed on 16 December 2003 under 37 CFR 1.131 has been considered but is ineffective to overcome the Marchese et al. reference with regard to lack of unity. Declaration of Yi Li is not persuasive because the claims fails to provide adequate support under 35 U.S.C. 112 for claims 29-32, 51-55, 64, 74-78, 97-101, 110, 120-123 and 127-128 of this application for the reasons provided below and in previous office actions. See MPEP 706.02. However, Examiner notes that the redacted information appears to be accurate.

Claim Rejections - 35 USC § 101

6. Claims 29-32, 51-55, 64, 74-78, 97-101, 110, 120-123 and 127-128 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

The reason for the rejection has been set forth in the previous office action.

Applicants argue that the antibodies of the invention are useful in the diagnosis and/or treatment of tumors, such as leukemia, and has specific and substantial utility. However, the post filing date reference information provides the missing information that was missing in the specification. At the time of the filing of the invention, the specification generically labels the claimed orphan receptor as a chemokine receptor but cannot provide specific function nor the experiment which links the orphan receptor to the function or treatment of tumor. It is only with the post filing date reference that one skilled in the art is aware of the treatment of tumor with the receptor which was

previous to the post filing date publication only known as an orphan receptor.

Furthermore, the specification does not provide the missing specific methods of the post filing date references which were necessary to determine the link to the leukemia.

Furthermore, at the filing date of the application, the specification lists many different diseases on pages 5 and 22 which have no nexus to treatment with the claimed receptor.

Therefore, the invention is not in readily available form. Instead, further experimentation of the protein itself was required before it could be used as shown by the post filing date reference. *Brenner V. Manson* 383 U.S. 519, 535-536, 148 USPQ 689, 696 (1966) stated that A Congress intended that no patents be granted on an chemical compound whose sole A utility \equiv consists of its potential role as an object of use-testing ... a patent is not a hunting license. \equiv *Brenner* further states that Alt is not a reward for the search, but compensation for its successful conclusion. \equiv

Claims 29-32, 51-55, 64, 74-78, 97-101, 110, 120-123 and 127-128 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

7. Claims 29-32, 51-55, 64, 74-78, 97-101, 110, 120-123 and 127-128 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not

described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

The reason for the rejection has been set forth in the previous office action.

Applicants argue that one skilled in the art can envision the antibodies or portions thereof of the invention that bind to the specified polypeptide fragments. However, one of skilled in the art cannot envision the full genus of antibodies which bind claimed variant molecules because the claims encompass antibody which bind variants whose structure is not known or other variant proteins with different function from SEQ ID NO:2 taught in the specification because the term "comprising" encompass structures which is not part of SEQ ID NO:2. Claimed antibody which bind protein variants encompass a large genus of antibodies which bind proteins or channels which are alleles or variants whose function has yet to be identified from different species of animal because the structure of the newly identified naturally occurring protein is not known. *University of California v. Eli Lilly and Co. (CAFC) 43 USPQ2d 1398* held that a generic claim to human or mammalian when only the rat protein sequence was disclosed did not have written description in the specification.

8. Claims 29-32, 51-55, 64, 74-78, 97-101, 110, 120-123 and 127-128 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the

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specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The reason for the rejection has been set forth in the previous office action.

Applicants argue that since the invention has utility for the arguments set forth in the 35 USC 101 rejection section that the knowledge of the ligand and tertiary structure is not necessary. However, as discussed above in the 35 USC 101 rejection the post filing date reference is not sufficient to overcome the rejection because the post filing date provides the necessary information which was not in the specification.

9. No claims are allowed.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Pak, whose telephone number is (571) 272-0879. The examiner can normally be reached on Monday through Friday from 8:30 AM to 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 272-0871.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Michael D. Pak

Michael Pak

Primary Patent Examiner

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29 March 2004